For	TIPET (	D-1449
рст	1 3 2005	in a

## U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. Serial No. 44657-AAA-PCT-US 10/052,961

Applicant:

NFORMATION DISCLOSURE CITATION Joseph R. Berger (Use several sheets if necessary) Filing Date Group January 18, 2002 **U.S. PATENT DOCUMENTS** Document Number Date Name Class Subclass Filing Date Examiner if Appropriate Initial 4/7/64 2 8 2 8 3 US 3 Pappo 10/24/95 US 5 4 6 1 0 3 0 Lindenbaum US 5 5 3 2 2 3 0 7/2/96 Daynes 7/13/99 US 5 9 2 2 7 0 1 Araneo US 8 2 8 3 1 3 12/7/04 Fishbein 6 FOREIGN PATENT DOCUMENTS Translation Document Number Date Country Class Subclass Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Protest Under 37 C.F.R. §1.291(a) filed on October 18, 1999 with the United States Patent and Trademark Office in connection with U.S. Serial No. 08/244,988, pp. 1-7, including a cover sheet, a Form PTO-1449, and Exhibits A-E March 2, 2000 Decision on Protest Under 37 C.F.R. §1.291(a) in connection with U.S. Serial No. 08/244,988, pp. 1-2, including a cover sheet, a Form PTO-892, Information on Submitting an INDA (2 pages), and a copy of 21 C.F.R. 312 (39 Pages) May 14, 1999 letter from the Department of Health and Human Services, Center For Drug Evaluation and Research, Rockville, Maryland, providing a "Copy of All Disclosable Approval Information For the Product Oxandrin, Manufactured by Biotechnology General," 30 pages Albanese, A.A., Lorenze, E.J., and Orto, L.A., (May 15, 1962) Nutritional and Metabolic Effects of Some Newer Steroids, Oxandrolone and Triamcinolone, New York State J. Med. 62:1607-1613 Albanese et al., (1970), "Steroid and Dietary Effects On Blood Lipids In Elderly Persons," Nutrition Reports International, Vol. 1, No. 4, pp. 231-242 Bailey, R.O., Turok, D.I., Jaufmann and Singh, J.K. (1987). Myositis and acquired immunodeficiency syndrome. Hum. Path. 18:749-751 Berger, J.R., (1991). Personal communication between Dr. Berger and Dr. Dudley of Gynex (letter dated July 6, 1991) Berkowitz, D., Clinical Investigator's Report, April 25,1962 Bessen, L.J., Greene, J.B., Louie, E., Seitzman, P., and Weinberg, H. (1988). Severe polymyositis-like syndrome associated with zidovudine therapy in AIDS and ARC. N. Eng. J. Med. 318:708 Blizzard, R.M., Hindmarsh, P.C. and Stanhope, R. (1991). Oxandrolone therapy: 25 years experience. Growth, Genet. Hor. 7:1-7 Chelbowski, R.T., Grosvenor, M.B., Bernhard, N.H., Morales, L.S. and Bulcavage, L.M. (1989). Nutritional status, gastrointestinal dysfunction and survival in patients with AIDS. Am. J. Gastroent. 84:1288-1293 Chernoff, D. (1990). Myositis in HIV-infected patients. In the AIDS Knowledge Base, Cohen, P.T., Sande, M.A. and Volberding, P.A. (eds.). Waltham, The Medical Publishing Group, pp. 5.14. 1-2 Dalakas, M.C., Pezeshkpour, G.H., Gravell, M. and Sever, J.L. (1986). Polymyositis associated with AIDS retrovirus. J. Amer. Med. Assoc. 256:2381-2383 Demling et al., (1996), "Use of Anticatabolic Agents For Burns," Current Opinion in Critical Care, Vol. 2, pp. 482-491 Demling, (1999), "Comparison of the Anabolic Effects and Complications of Human Growth Hormone and the Testosterone Analog, Oxandrolone, After Severe Burn Injury," Burns, Vol. 25, pp. 215-221

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant: Joseph R. Berger U.S. Serial No.: 10/052,961 Filed: January 18, 2002 Exhibit A

	Form PTO-1
6	TPE
•	杨
	7 13 2005 W
0	7 13 [003 8]
h	\$
< ₫	70.00

449

## U.S. Department of Commerce Patent and Trademark Office

 Atty. Docket No.
 Serial No.

 44657-AAA-PCT-US
 10/052,961

Applicant:

(Use several sheets if necessary)

Joseph R. Berger

Eiling Date

Filing Date Group January 18, 2002

January 18, 2002 PADEMA **U.S. PATENT DOCUMENTS** Class Subclass Filing Date Document Number Date Examiner Name if Appropriate Initial FOREIGN PATENT DOCUMENTS Translation Class **Subclass** Document Number Date Country Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Demling and DeSanti, (2001), "The Rate of Restoration of Body Weight After Burn Injury, Using the Anabolic Agent Oxandrolone, is not Age Dependent," Burns, Vol. 17, pp. 46-51 Draft of G.D. Searle & Co., (1962), Physicians' Product Brochure No. 43, "ANAVAR® Brand of Oxandrolone, For Protein Tissue Building and Anabolism," 16 pages with a 5 page insert FDA approved Physician's Product Brochure No. 43 for ANAVAR® Brand of Oxandrolone, including Package Insert, G.D. Searle (1964) Fox et al., (1962), "Oxandrolone: A Potent Anabolic Steroid of Novel Chemical Configuration," J. Clin. Endocrinol. Metab., Vol. 22, pp. 921-924 Garlick et al., (October 1988), "Regulation of Muscle Protein Turnover: Possible Implications For Modifying the Responses to Trauma and Nutrient Intake," in Bailliere's Clinical Gastroenterology, Bailliere Tindall, London/Philadelphia/ Sydney/Tokyo/Toronto, Burns ed., Vol. 2, No. 4, pp. 915-940 Gold, E.M., Clinical Investigator's Report, May 31, 1962 Gonzales, M.F., Olney, R.K., So, Y.T., Greco, C.M., et al. (1988). Subacute structural myopathy associated with human immunodeficiency virus infection. Arch. Neurol. 45:585-587 Gorard, D.A., Henry, K., and Guiloff, R.J. (1988). Necrotizing myopathy and zidovudine. Lancet. 1:1050-1051 Haupt et al., (1984), "Anabolic Steroids: A Review of the Literature," The American Journal of Sports Medicine, Vol. 12, No. 6, pp. 469-484 Heller, C.G., Clinical Investigator's Report, June 20, 1962 Hellerstein, M.K., J. Mudie, H. and Viteri, F. (1990). Current Approach to the treatment of human immunodeficiency virus-associated weight loss: pathophysiologic considerations and emerging management strategies. Sem. Oncol. 17:17-33 Hernon et al., (June 1987), "Treatment of Burns," in Current Problems in Surgery, Year Book Medical Publishers, Inc., Chicago, Ravitch et al., eds., Vol. 24, No. 6, pp. 347-397 Hughes, B.J. and Kreig, M. (1988). Steroid receptors and the muscular system. In, Steroid Receptors and Disease, Sheridan, P.J. Blum, K. and Trachtenberg, M.C. (eds). Marcel Dekker, Inc., New York, pp. 415-433 Jones, R.W.A., El Bishti, M.M., Bloom, S.R., Burke, J., Carter, J.E., et al (1980). The effects of anabolic steroids on growth, body composition, and metabolism in boys with chronic renal failure on regular hemodialysis. J. Pediat. 97:559-566 Karim et al., (1973), "Oxandrolone Disposition and Metabolism In Man," Clin. Pharmacol. Ther. Vol. 14, No. 5, pp. 862-869 Kasler, M.H., Clinical Investigator's Report, March 16, 1962 Kotler, D.P., Wang, J. and Pierson, R.N. (1985). Body composition studies in patients with acquired immunodeficiency syndrome. Am. J. Clin. Nutr. 42:1255-1265

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTC	0-1449 U.S. Dep	Commerce Office		ocket No. AAA-PCT-US	• • • • • • • • • • • • • • • • • • •		
	2 NEORMATION I			Applica Joseph	nnt: R. Berger		
OCT 13 201	(Use several	sheets if no	ecessary)	Filing I	<del>v</del>	Group	p
PADEMA	,07	HS DAT	TENT DOCUMENTS				
Examiner	Document Number	Date	Name	Class	Subclass	Filing l	
Initial	<del>-                                     </del>					if Appr	opriate
		FORFICNI	PATENT DOCUMEN	TS	· <del></del>		
	Danumant Number	Date		Class	Subclass	Transla	
	Document Number	Date	Country	Class	Subciass	<b></b>	T
						Yes	No
	OTHER DOCUME	NTS (Includi	ng Author, Title, Date	Dortingnt	Pages Eta )		<u></u>
	Kotler, D.P., Tierney, A.F	R., Wang, J., a	nd Pierson, R.N. (1989)	. Magnitude	of body-cell-ma	ss depleti	ion and
	the timing of death wastir	ig in AIDS. Ai	n. J. Clin. Nutr. 50:444-	-447			
	Kowalewski and Heron, (					In Rats, T	reated
	Or Not With An Anabolic Leevy, C.M., Clinical Inv			oi. 64, pp. 3	41-34/		
	Marmo et al., (February 1			e Pharmacoo	lynamic Effects	Nor-19-	
	Androstenolone Undecyla						3, No.
	2, pp. 47-56	15 15	(1000) G. P.	1 12	L. II. Constant		· - /
	Masse, R.B.H., Ayotte, C spectrometric characteriza	. and Dugal, R	. (1989). Studies on ana rolone urinary metabolit	ibolic steroid tes in man. P	is II – Gas chrom liomed, Environ.	natograpn Mass Sr	nc/mass
	(England) 18:429-438	ition of oxund	tolone urmary measons				
	Mendenhall, C.L., Anders survival in patients with a 311:1464-1470						
	Mendenhall, C.L., Grossn function: differences betw	nan, C.J., Rose een analogues	elle, G.A., et al. (1990). L. J. Steroid Biochem. M	Anabolic ste lolec. Biol. 3	roids effects on 7:71-76, (Exhib	immune it 42);	
	Mensch, M., Clinical Inve						
	Metcalf, W., Clinical Inve	stigator's Rep	ort, July 14, 1961				
	Meyers, F.H., Jawetz, E. a		A. (1980). Review of M	edical Pharn	nacology. Califor	rnia: Lan	ge
	Medical Publications, p. 4 O'Shea et al., (December	1970) "Bioch	emical and Physical Effe	ects of An A	nabolic Steroid I	In Compe	etitive
	Swimmers and Weightlift	ers," Nutrition	Report International, V	ol. 2, No. 6,	pp. 351-361	Облара	
	Pan, C.S., Inadomi, D.W., muscle protein synthesis i	Laidlaw, S.A n acutely uren	., Jones, M.R., and Kopnic rats. Kidney Intl. 25:	ple, J.D. (19	84). Oxandrolon	e enhanc	es
	Paulsen, C.A., Clinical In			1040	1041	<del></del>	
	Physicians' Desk Referen Roubenoff and Kehayias,					" Nutriti	On.
	Reviews, Vol. 49, No. 6, j		The Meaning and Meas	surcincin of i	Scall Body Widss	, munici	OII
	Ruffin, J.M., Clinical Inve	stigator's Rep	ort, March 20, 1962				
	Selye, (1970), "Prevention		cin-Induced Intestinal (	JIcers by Va	rious Catatoxic S	Steroids,'	'Exp.
	Med. Surg., Vol. 28, pp. 1	69-78				4h amal	voia af
	Simpson, D.M. and Bende 11 patients. Ann. Neurol.		). Human immunoderici	ency virus-a	ssociated myopa	iiiiy. anai	ysis oi
	Solymoss et al., (1971), "1	Protection by S				gitoxin o	r
	Indomethacin Intoxication	," Toxicol. Ap	opl. Pharmacol., Vol. 18	s, pp. 586-92			
	Stern, R., and Gold, J. and syndrome. Muscle Nerve.	l DiCarlo, E.F. 10:318-322	. (1987). Myopathy com	iplicating the	acquired immui	ne deficie	ncy
EXAMINER	primi one. Masere iverve.	DATE CONSI	DERED				
*EXAMINER:	Initial if citation considered, when	her or not citatio	n is in conformance with M	PEP 609: Drav	v line through citation	on if not in	1
conformance an	d not considered. Include copy of	uus ionn with ne	At communication to applica	aitt.			

6	Form PTO-1	449
00	T 13 2005 W	IN
<b>S</b>	, E/	

## U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)

Atty. Docket No.	Serial No.
44657-AAA-PCT-US	10/052,961
Applicant:	

Applicant: Joseph R. Berger

Filing Date January 18, 2002 Group

TRADEMAT						U.S. PA	FENT DOCUMENT	`S		<del>,</del>		
Examiner Initial	Doc	umen	t Nur	mber	•	Date	Name	Class	Subclass	Filing Date if Appropriate		
						<u> </u>			1			
						FOREIGN	PATENT DOCUME	NTS		_		
	Doc	umen	t Nur	mber		Date	Country	Class	Subclass	Transla	ation	
										Yes	No	
							<u> </u>		<u></u>		<u></u>	
		ОТН	ERI	OOC	UME	NTS (Includ	ing Author, Title, Da	ate, Pertinent F	Pages, Etc.)			
							paches to Nutritional S	Support in Canc	er," Current Op	inion in		
	Oncology, Vol. 5, pp. 633-638 Wilson, (1990), "Androgens," in Goodman and Gilman's, The Pharmacological Basis of Therapeutics, Eight											
	Edit	ion, Pe	ergan	non F	ress, ì	New York, p	p. 1413-1430					
	Wol	fe, (19	986), ' icina	"Nut	rition a	and Metaboli	sm in Burns," in, Crit hernow B. and Shoen	ical Care State	of the Art, Socie	ety of Cri	tical	
							Report, April 27,1962		, voi. 7, pp. 19	<u> </u>		
					-					-		
				•							•	
										<del></del> -		
		-										
EXAMINER	1 ,					DATE CONSI	DERED					
EXAMINER:	Initial if	citation	n consi	iderec	i, wheth	er or not citation	on is in conformance with ext communication to app	MPEP 609: Draw	line through citati	on if not in	1	

											<b>,</b>		
Form PT		19						Department of Co		Atty. Do 4657-AA	cket No. A-PCT-US	Serial No. Not Yet I	-
40	INFO	RN	ЛA	TIO	ON			LOSURE CITATI		Applicar Joseph	R. Berge	r	
7 13 7005 C								ets if necessary)		Filing Da		Group	
A TRADE	<u> </u>	•					ı	U.S. PATENT DO	CUMENTS				
Examiner Initial		Do	cum	ent	Nur	nbei	•	Date	Name	Class Subclass			Filing Date if Appropriate
		_		_	-		L			<del>                                     </del>			
					-		_						<u></u>
		-	-	-	$\vdash$	ļ				1			
					<u> </u>	F	OI	REIGN PATENT	DOCUMEN	TS			
	D	ocı	ıme	ent	Nu	mb	er	Date	Country	Class	Subclass	Trans	lation
												Yes	No
	0	2	2	2	3	8	5	February 3, 1993	Europe	<u> </u>		ļ	
					-		-			1			
(	THE	R	DO	CU	MI	EN'	ΓS	(Including Author	r, Title, Date	, Pertin	ent Pages	, Etc.)	
	Chi	icag	о Т	ribı	ıne,	Se	oter	nber 20, 1991, North	Sports Final	edition, I	Business Se	ction, pa	ge 1
	1		dale .143	-			a P	harmacopoeia, The F	Pharmaceutical	l Press, L	ondon, Re	ynolds, et	t al.,
	Phy	/sic	ians	, D	esk	Re	fere	nce (1988), 42 <sup>nd</sup> Edit	tion, cover pag	ge and pa	ges 1975-1	976	
								15, August 28, 1991 's, AIDS"	"Gynex obtain	s interna	tional righ	ts to drug	to
	Arc	ons	aku	1, C	her	nica	ıl A	bstracts, Vol. 115: 1	51902q, 1988				
	Lor	ie, e	t al.	., C	hen	nica	l A	bstracts, Vol. 107: 1'	74950c, 1987				

EXAMINER DATE CONSIDERED

O'Shea, et al., Chemical Abstracts, Vol. 74: 75106a, 1971

Endo, Chemical Abstracts, Vol. 73: 95098g, 1970

Boris, et al.,

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Chemical Abstracts, Vol. 74: 72305d, 1971

Kopera, H. Acta Endocrinologica 1985, Supplementum 271, pp. 11-18

Applicant: Joseph R. Berger U.S. Serial No.: 10/052,961 Filed: January 18, 2002 Exhibit B

Form PTO-1449							of Commerce emark Office	Atty. 44647-AA US/JPW/	A-PCT-	Serial No. 10/052,961					
(137005)	ENI	O	RM	<b>A</b> T	ſΙO	N ]	DIS	CL	OSURE C	CITATION	Applicants  Joseph R.				
p~ <i>.§</i>						era	l sh	eet	s if necessa	ary) 	Filing Dat		Group		
AT & TRADE									U.S. PA	TENT DOCUME	NTS				
Examiner Initial			Doc	um	ent i	Nun	nber		Date	Name	Class	Subclass	Filing Dail		
		6	0	9	0	7	9	9	7/18/2000	Berger					
						-		-							
								L_				<u> </u>			
Ī		_				<b>N</b> 1			r	PATENT DOCU	MENTS Class	Subclass	T		
	Document Number	ег	Date	Country	Class	Subclass	Yes	nslation No							
										, se-		<del> </del>	165	110	
												<u> </u>			
									·	ling Author, Title, D					
	1								hibit 2)	ecember 22, 1999	, now anow	ed, including	, a courte	sy copy	
		liic	and	<u> </u>		1411	113 (	(LA	more 2)			···			
	Ì														
						-									
	ľ														
	[														
					<u></u>						<del></del>		·		
	}														
	- 1											: Joseph R. Berge			

EXAMINER DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Exhibit C